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MAY 14 2008

# 510 (k) Summary of safety and effectiveness

## SUBMITTER INFORMATION

| | | |
|---|---|---|
| A. | Company Name: | T.F.I. System s.r.l. |
| B. | Company Address: | Via Alessandro D'Ancona, 23<br>Roma, Italy 00137 |
| C. | Company Phone:<br>Company Fax: | +39 06 87201371<br>+39 06 87232518 |
| D. | Contact Person: | Claudio Mechelli<br>Managing Director<br>T.F.I. System s.r.l.<br>E mail info@tfisystem.it |
| E. | Date Summary Prepared: | December 20, 2007 |

## DEVICE IDENTIFICATION

| | | |
|---|---|---|
| A. | Device name: | Endosseous Dental Implant System |
| B. | Trade/Proprietary Name: | EASY GRIP® dental implant system |
| C. | Classification name: | Endosseous dental implant (21 CFR 872.3640) and<br>Endosseous dental implant abutment (21 CFR 872.3630) |
| D. | Product Code: | DZE |

## LEGALLY MARKETED DEVICES (PREDICATE DEVICES)

- Straumann USA & AG, ITI® Dental Implant Systems K033922, K984104, K003271, K012757, K030007, K031055,
- Sudimplant SA, T.B.R.® ide@ conic, K050956,
- ACE Surgical Supply Co., Inc., ACE CONNECT ™ Internal Connection Screw Dental Implant System K041759,
- Implant Innovations, Inc., 3i Restorative Dental Implant Systems, K041402, K063286, K022009,
- SIC Invent AG, SIC Dental Implant Systems, K040757, K061500,
- FRIADENT GmbH, XIVE® Dental Implant Systems, K013867, K021318, K024004

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## DESCRIPTION OF THE DEVICE

EASY GRIP dental implants are root-form endosseous dental implant devices made out of biocompatible medical titanium, commercially pure or alloyed. There are three types of implants: cylindrical, anatomical, conical, available in different diameters from 3.3 to 5.5 mm and lenghts that vary from 8 to 16 mm. The anchorage surface of the implant is roughened by a sand-blasting and an acid-etching process, for better osseointegration. This submission also include compatible screws and prosthetic components.

## INTENDED USE

EASY GRIP implants are designed for use in partially or totally edentulous mandibles or maxillae for attachment of complete denture prostheses or as a terminal or intermediary abutment for fixed or removable bridgework or as a free-standing single tooth replacement. EASY GRIP implant system uses a two-stage implantation procedure or one-stage procedure.

## SUBSTANTIAL EQUIVALENCE

EASY GRIP dental implant system and the predicate devices are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium with roughened surfaces. The subject and predicate devices use the same materials and are similar in size. In further support of a substantial equivalence determination, Section 5 provides a comparison chart of the Easy Grip implant system and the predicate devices.

Based on the available 510(k) summaries and the information provided herein, we conclude that Easy Grip implant system is substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

Mr. Claudio Mechelli
Managing Director
T.F.I. System Srl
Via Alessandro D'Ancona, 23
00137 Roma
ITALY

Re: K073622
Trade/Device Name: Easy Grip
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 18, 2008
Received: April 24, 2008

Dear Mr. Mechelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

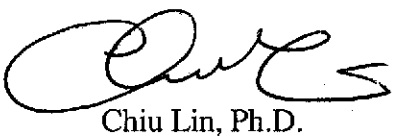
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: EASY GRIP

Indications for Use:

EASY GRIP implants are designed for use in partially or totally edentulous mandibles or maxillae for attachment of complete denture prostheses or as a terminal or intermediary abutment for fixed or removable bridgework or as a free-standing single tooth replacement. EASY GRIP implant system uses a two-stage implantation procedure or one-stage procedure.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K073622